

AMENDMENT AND RESPONSE TO OFFICE ACTION AND
PETITION FOR ONE-MONTH TIME EXTENSION
U.S. Serial No. 10/607,010

SUMMARY OF MARCH 22, 2007 INTERVIEW

A telephone interview was conducted on March 22, 2007 with Examiner Shaffer and Geoffrey Gavin (Reg. No. 47,591), a representative of the Assignee, participating. Claims 1 and 18 and the Faccioli reference were discussed. Specifically, the pivot arm of claim 1 and transverse translation of its ends with respect to one another and the longitudinal axis of the pivot arm was discussed. For claim 18, the coupling between the pivot arm and pin clamp was discussed, including the claimed groove and locator pin.

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REMARKS

Assignee and the undersigned attorney thank Examiner Shaffer for his review of this patent application. Claims 6-16, 22, 26, and 27 are cancelled above, and claims 35 and 37-40 were previously cancelled. Claims 1, 18-21, 23, 25, 30, 33, and 34 are amended above, and claims 42 and 43 are added. No new matter has been added by the claim amendments. Assignee respectfully requests reconsideration of claims 1-5, 17-21, 23-25, 28-34, 36, and 41 and consideration of claims 42 and 43.

Claim Rejections

In the Action, the Examiner rejected claims 1-3, 5, 16-19, 21, 23, 30-34, 36, and 41 under 35 U.S.C. § 102(b) as being anticipated by PCT Publication No. WO 00/40163 to *Faccioli et al.* (“*Faccioli*”). The Examiner rejected claims 24, 25, 28, and 29 under 35 U.S.C. § 103(a) as being unpatentable over *Faccioli* in view of U.S. Patent No. 5,160,335 to *Wagenknecht* (“*Wagenknecht*”). The Examiner rejected claims 4 and 20 under 35 U.S.C. § 103(a) as being unpatentable over *Faccioli* in view of U.S. Patent No. 5,405,347 to *Lee et al.* (“*Lee*”). Finally, the Examiner rejected claims 25, 28, and 29 under 35 U.S.C. § 112, first paragraph. Claim 25 is amended to obviate this rejection, and thus the § 112 rejection of claims 25, 28, and 29 should be withdrawn.

Claims 1-5, 17, 34, 36, and 41

Amended claim 1 recites:

An external fixation apparatus comprising:
a first member attachable to a first bone segment through a pin;
a lockable ball joint connected to the first member;

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a pivot arm connected attachable to the first member through the lockable ball joint, the pivot arm comprising a first end portion and a second end portion, wherein the first end portion and the second end portion are configured to translate may be translated transversely relative to one another and to a longitudinal axis of the pivot arm; and

a pin clamp coupled to and rotatable about the second end portion of the pivot arm through a lockable joint, the pin clamp being attachable to a second bone segment.

The Examiner asserts that *Faccioli* teaches each and every element of claim 1. However, *Faccioli* fails to teach or suggest each and every element of amended claim 1. More particularly, *Faccioli* does not teach or suggest a pivot arm with first and second end portions that are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm.

As mentioned in the prior response, one example of the claimed pivot arm is shown in Figs. 1 and 3 and described at pages 11-12 of the application. More specifically, end 118 moves “either medially or laterally relative to both the longitudinal axis of second member 110 and end 116, depending on the direction in which worm gear 132A is turned [and turning worm gear 132B moves] end 116 either posterior or anterior relative to the longitudinal axis of second member 110 and end 118” (See page 12, lines 5-11.)

In the Action, the Examiner refers primarily to Figures 2 and 2B of *Faccioli* and the associated description of these drawings. With respect to claim 1, the Action does not address the “pivot arm” recited in claim 1, instead suggesting that reference numerals 2, 20, and 35 of *Faccioli* comprise a “second member,” which is no longer recited in claim 1.

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As set forth in claim 1, the second end portion of the pivot arm is coupled to the pin clamp, and the pin clamp is rotatable about the second end portion of the pivot arm. In view of this limitation, the only structure of *Faccioli* that could conceivably be the claimed pivot arm is stem 20 of *Faccioli*. Moreover, as discussed during the March 22 interview, stem 20 of *Faccioli* does not teach or suggest the “pivot arm” of claim 1 because the recited pivot arm has first and second end portions that “are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm.” In contrast, the ends of stem 20 of *Faccioli* are clearly in a fixed relationship with respect to one another. As such, *Faccioli* does not teach or suggest each and every limitation of amended claim 1, and thus the § 102 rejection should be withdrawn.

Furthermore, *Lee* fails to teach or suggest a pivot arm with first and second end portions that are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm, either alone or in combination with *Faccioli*. The adjustable connector 10 of *Lee*, which includes lateral adjustment mechanism 12 and angular adjustment mechanism 70, is used to connect two external fixator rods and to improve movement of the two fixator rods with respect to one another. The connector of *Lee* includes openings in each end for the insertion of such rods. *Lee* does not teach any mechanism by which ends of a structure, such as a pivot arm, are configured to translate transversely with respect to one another and its longitudinal axis.

The Action currently cites *Lee* in combination with *Faccioli* in rejecting claims 4 and 20 as obvious under 35 U.S.C. § 103, stating that: “It would have been obvious to one of

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ordinary skill in the art to have provided the device of Lee et al. between elements (2 and 20/replacing the ball and socket joint found there) to allow for minor adjustments to fully align bone fragments without detaching the device from itself or the bone pins.” (Office Action, p. 5.) However, as noted above and discussed in the March 22 interview, reference numerals 2 and 20 of *Faccioli* cannot combine to form the recited “pivot arm.” Thus, placing the angular and lateral adjustment mechanism of *Lee* between the central body 2 and stem 20 of *Faccioli* does not form the invention recited in claim 1. Moreover, one would have to saw the stem 20 of *Faccioli* in half and insert the adjustable connector 10 of *Lee* in between the two halves (along with making innumerable other modifications) to remotely approach the subject matter of claim 1, and there is no teaching, suggestion, or motivation in either *Faccioli* or *Lee* or elsewhere in the prior art to do so.

For the above reasons, the Examiner should withdraw the rejection of claim 1, and claim 1 should be allowed. Inasmuch as claims 2-5, 17, 34, 36, and 41 depend from and thereby include the limitations of claim 1, claims 2-5, 17, 34, 36, and 41 should also be allowed for at least such dependencies.

Claims 18, 19, 21, 23, and 24

Amended claim 18 recites:

An external fixation apparatus comprising:

a first member attachable to a first bone segment through a pin;
a lockable ball joint connected to the first member;
a pivot arm connected second member attachable to the first member through the lockable ball joint, the pivot arm second member comprising a first end portion and a second end portion, the second end portion comprising a shaft extending transversely therefrom with a at least one

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groove extending substantially around ~~at least~~ a portion of a circumference of the shaft, and wherein the first and second end portions are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm; and

~~a pin clamp attachable to a second bone segment and releasably snap fit coupled to and rotatable about the shaft extending from the pivot arm second member, the pin clamp comprising:~~

~~a first jaw and a second jaw, the first jaw including a hole that receives the shaft; and~~

~~a locator pin that is received within the at least one groove of the shaft to releasably couple when the pivot arm second member and the pin clamp are coupled and removed from the groove to disengage the pin clamp from the pivot arm;~~ and

~~a first bolt that passes through openings in the first and second jaws such that tightening of the first bolt interferes with the shaft and locks rotation of the pin clamp about the second member.~~

The Examiner asserts that *Faccioli* teaches each and every element of claim 18, but *Faccioli* does not teach or suggest each and every limitation of amended claim 18 for reasons similar to those described above with respect to claim 1. Specifically, *Faccioli* fails to teach or suggest the pivot arm with first and second end portions that are configured to translate transversely relative to one another and to a longitudinal axis of the pivot arm, as recited in amended claim 18.

Additionally, *Faccioli* does not teach or suggest (a) a pivot arm with a second end portion that has a shaft extending transversely therefrom with a groove extending substantially around a circumference of the shaft, (b) a pin clamp that is releasably snap fit to and rotatable about the shaft extending from the pivot arm, or (c) a locator pin that is received within the groove of the shaft when the pivot arm and the pin clamp are coupled and removed from the groove to disengage the pin clamp from the pivot arm.

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The Action asserts that pivot 35 of *Faccioli* teaches the recited shaft of claim 18. However, pivot 35 includes only a hole and does not include a “groove extending substantially around a circumference of the shaft” recited in amended claim 18.

Additionally, *Faccioli* does not teach a pin clamp that is releasably snap fit to a shaft extending from the pivot arm. The present application describes several embodiments of a pin clamp coupled to a pivot arm, including embodiments where the pin clamp is removably “snap fit” to a shaft extending from an end of the pivot arm. (See page 20, lines 7-15; page 22, line 4 – page 23, line 5; Figs. 15-19.) The Action asserts that lockpins 37 of *Faccioli* could inherently be pulled out and the pin clamp of *Faccioli* decoupled from stem 20. Even if this is so, upper jaw 40 (and thus the *Faccioli* pin clamp) is journaled between prongs 23 and 24 of stem 20 and is not releasably snap fit to stem 20, as recited in amended claim 18. Furthermore, *Faccioli* does not teach a locator pin received within the groove of the shaft when the pivot arm and the pin clamp are coupled and removed from the groove to disengage the pin clamp from the pivot arm, as removal of the lockpins 37 altogether would merely result in pivot 35 being less secure between the prongs, but the jaws 40 and 50 of the *Faccioli* clamp would still be coupled to pivot 35.

For all of the above reasons, the Examiner should withdraw the rejection of claim 18 as anticipated by *Faccioli*, and claim 18 should be allowed. Inasmuch as claims 19, 21, 23, and 24 depend from and thereby include the limitations of claim 18, claims 19, 21, 23, and 24 should also be allowed for at least such dependencies.

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Claims 25, 28, 29, 42, and 43

Amended claim 25 recites:

An external fixation system for attaching pins or wires to at least one bone segment, the system comprising:

a first member;

a second member coupled to the first member, the second member comprising a shaft that extends transversely from an end portion of the second member and has a at least one groove extending substantially around at least a portion of a circumference of the shaft; and

a pin clamp snap fit onto the shaft of the second member, the pin clamp comprising:

a first jaw and a second jaw, each of the first and second jaws having openings;

biasing elements received within the openings, the biasing elements adapted to bias the first and second jaws toward each other;

first and second bolts that extend into the openings in the first and second jaws, the first and second bolts adapted to compress the biasing elements and hold the first and second jaws together;

a hole in the first jaw configured to receive the shaft; and a push or pull mechanism comprising a locator pin that is received within the at least one groove of the shaft to releasably couple when the pivot arm second member and the pin clamp are coupled and removed from the groove to disengage the pin clamp from the pivot arm.

The Examiner asserts that claim 25 is obvious in view of *Faccioli* combined with *Wagenknecht*. However, for reasons similar to those described above with respect to only claim 18 (but not claim 1), the cited references, either alone or in combination, fail to teach a (a) second member with a shaft that extends transversely from an end portion of the second member and has a groove extending substantially around a circumference of the shaft, (b) a pin clamp snap fit onto the shaft of the second member, or (c) a push or pull mechanism comprising a locator pin that is received within the groove of the shaft when the pivot arm

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and the pin clamp are coupled and removed from the groove to disengage the pin clamp from the pivot arm.

For the above reasons, the Examiner should withdraw the rejection of claim 25 as obvious in view of the combination of *Faccioli* and *Wagenknecht*, and claim 25 should be allowed. Inasmuch as claims 28, 29, 42, and 43 depend from and thereby include the limitations of claim 25, claims 28, 29, 42, and 43 should also be allowed for at least such dependencies.

Claims 30-33

Amended claim 30 recites:

A method of treating a skeletal condition or injury using an external fixation apparatus, the method comprising:

- (a) fixing a first member to a first side of a fracture with upper bone pins;
- (b) fixing a pin clamp to a second side of the fracture with lower bone pins; and
- (c) coupling the pin clamp to the first member through the use of a pivot arm having first and second end portions, the first member being coupled to the first end portion through a lockable ball joint and the pin clamp being coupled to the second end portion through a second lockable joint; and
- (d) adjusting the first and second end portions of the pivot arm relative to each other and transversely relative to a longitudinal axis of the pivot arm to precisely reduce the fracture.

For reasons similar to those described above with respect to apparatus claim 1, *Faccioli* does not teach or suggest each and every element of amended method claim 30. More specifically, *Faccioli* does not teach or suggest adjusting the first and second end portions of a pivot arm relative to each other and transversely relative a longitudinal axis of the pivot arm.

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For these reasons, the Examiner should withdraw the rejection of claim 30 as anticipated by *Faccioli*, and claim 30 should be allowed. Inasmuch as claims 31-33 depend from and thereby include the limitations of claim 30, claims 31-33 should also be allowed for at least such dependencies.

Conclusion

The foregoing is submitted as a full and complete response to the Action mailed December 19, 2006. Assignee submits that claims 1-5, 17-21, 23-25, 28-34, 36, and 41-43 are in condition for allowance, and notice of allowance is respectfully requested. The preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability. If the Examiner believes there are any issues that can be resolved via a telephone conference, or there are any informalities that can be corrected by an Examiner's amendment, please call Geoffrey Gavin at (404) 815-6046.

Other than the fee for the one month extension of time, the undersigned attorney believes no fees are due; however, the Commissioner is authorized to debit deposit account no. 11-0855 to the extent necessary if other fees are due.

Respectfully submitted,



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